Senate

General Assembly

File No. 115

January Session, 2013

Substitute Senate Bill No. 955

Senate, March 25, 2013

The Committee on Insurance and Real Estate reported through SEN. CRISCO of the 17th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING PHARMACY AUDITS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective October 1, 2013*) (a) As used in this section:

(1) "Extrapolation" means the practice of inferring a frequency of dollar amount of overpayments, underpayments, nonvalid claims or other errors on any portion of claims submitted, based on the frequency or dollar amount of overpayments, underpayments, nonvalid claims or other errors actually measured in a sample of claims;

(2) "Pharmacy audit" means an audit, conducted on-site or remotely by or on behalf of a pharmacy benefits manager or plan sponsor of any records of a pharmacy for prescription drugs or prescription devices dispensed by such pharmacy to beneficiaries of a health benefit plan. "Pharmacy audit" does not include (A) a concurrent review or desk audit that occurs within three business days of the pharmacy's

transmission of a claim to a pharmacy benefits manager or plan sponsor, or (B) a concurrent review or desk audit where no charge-back or recoupment is demanded by the pharmacy benefits manager or plan sponsor;

(3) "Plan sponsor" has the same meaning as described in section 38a-479aaa of the general statutes, as amended by this act.

(b) (1) No entity other than a pharmacy benefits manager or a plan sponsor shall conduct a pharmacy audit unless such entity and manager or sponsor, as applicable, have executed a written agreement for the conducting of pharmacy audits. Prior to conducting a pharmacy audit on behalf of such manager or sponsor, such entity shall notify the pharmacy in writing that such entity and manager or sponsor, as applicable, have executed such agreement.

(2) Any entity conducting a pharmacy audit shall have access only to previous pharmacy audit reports of a particular pharmacy conducted by or on behalf of such entity. Nothing in this subdivision shall be construed to authorize access to any information that is confidential or prohibited from disclosure by law.

(3) Any information collected during a pharmacy audit shall be confidential by law, except that the entity conducting the pharmacy audit may share such information with the pharmacy benefits manager and the plan sponsor, for which such pharmacy audit is being conducted.

(4) No entity conducting a pharmacy audit shall receive payment or any other consideration on any basis that is based on the amount claimed or the actual amount recouped from the pharmacy being audited.

(c) (1) Any entity conducting a pharmacy audit shall:

(A) Provide the pharmacy being audited at least fourteen calendar days' prior written notice before conducting a pharmacy audit;

(B) Not initiate or schedule a pharmacy audit during the first five business days of any month, unless expressly agreed to by the pharmacy being audited;

(C) Make all determinations regarding the validity of a prescription or other record consistent with sections 20-612 to 20-623, inclusive, of the general statutes;

(D) Accept paper or electronic signature logs that document the delivery of prescription drug and device and pharmacist services to a health plan beneficiary or such beneficiary's agent;

(E) Provide to the pharmacist in charge, prior to leaving the pharmacy at the conclusion of an on-site portion of a pharmacy audit, a complete list of records reviewed; and

(F) Establish a process for a pharmacy to appeal a final pharmacy audit report and disclose such procedures to the pharmacy being audited.

(2) Any pharmacy audit that involves clinical judgment shall be conducted by or in consultation with a licensed pharmacist.

(3) No pharmacy audit shall cover a period of more than twenty-four months after the date a claim was submitted by the pharmacy to the pharmacy benefits manager or plan sponsor unless a longer period is required by law.

(d) (1) (A) Not later than sixty calendar days after an entity concludes a pharmacy audit and before such entity issues a final pharmacy audit report, such entity shall provide a preliminary pharmacy audit report to the pharmacy. Such entity shall provide such pharmacy with not less than thirty calendar days after such pharmacy receives such preliminary report to respond to the findings in such report, including addressing any alleged mistakes or discrepancies and producing documentation to that effect.

(B) To validate the pharmacy record and delivery, a pharmacy may

use authentic and verifiable statements or records, including, but not limited to, medication administration records of a nursing home, assisted living facility, hospital or health care provider with prescriptive authority.

(C) To validate claims in connection with prescriptions or changes in prescriptions, or refills of prescription drugs, a pharmacy may use any valid prescription, including, but not limited to, medication administration records, facsimiles, electronic prescriptions, electronically-stored images of prescriptions, electronically-created annotations or documented telephone calls from the prescribing health care provider or such provider's agent. Documentation of an oral prescription order that has been verified by the prescribing health care provider shall meet the provisions of this subparagraph.

(D) If an entity conducting a pharmacy audit uses extrapolation to calculate penalties or amounts to be charged back or recouped, the pharmacy may present evidence to validate orders for prescription drugs or prescription devices that are subject to invalidation due to extrapolation.

(2) (A) Not later than one hundred twenty calendar days after any responses from the pharmacy under subdivision (1) of this subsection are received by the entity conducting the pharmacy audit or, if no such responses are received, after the entity concludes a pharmacy audit, such entity shall issue a final pharmacy audit report that takes into consideration any responses provided to such entity by the pharmacy.

(B) A pharmacy may appeal a final pharmacy audit report in accordance with the procedures established by the entity conducting the pharmacy audit, provided the time period for filing such appeal is not less than thirty calendar days after such pharmacy receives such final report.

(C) After an appeal under subparagraph (B) of this subdivision has been decided, the entity that issued the final pharmacy audit report shall provide a written determination of the appeal together with the

final pharmacy audit report to the pharmacy and, if applicable, the pharmacy benefits manager and the plan sponsor. If the pharmacy, pharmacy benefits manager or plan sponsor is not satisfied with such determination, such pharmacy, manager or sponsor may seek relief pursuant to the terms of the contract between such pharmacy and such manager or sponsor.

(e) (1) No pharmacy shall be subject to charge-back or recoupment for a clerical or recordkeeping error in a required document or record, including a typographical error, scrivener's error or computer error, unless such error resulted in actual financial harm to the pharmacy benefits manager, plan sponsor or a plan beneficiary.

(2) No entity conducting a pharmacy audit or person acting on behalf of such entity shall charge-back or recoup, attempt to charge-back or recoup, or assess or collect penalties from a pharmacy until the time period to file an appeal of a final pharmacy audit report has passed or the appeals process has been exhausted, whichever is later. If an identified discrepancy in a pharmacy audit exceeds thirty thousand dollars, future payments to the pharmacy in excess of such amount may be withheld pending adjudication of an appeal. No interest shall accrue for any party during the audit period, beginning with the notice of the pharmacy audit and ending with the conclusion of the appeals process.

(f) The provisions of this section shall not apply to a pharmacy audit conducted because a pharmacy benefits manager, a plan sponsor, an entity acting on behalf of such manager or sponsor or an employer covered under a health benefit plan has indications that support a reasonable suspicion that the pharmacy being audited is or has been engaged in criminal wrongdoing, wilful misrepresentation or fraud.

Sec. 2. Section 38a-479aaa of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2013*):

As used in this section and sections 38a-479bbb to 38a-479hhh, inclusive, as amended by this act, and section 1 of this act:

(1) "Commissioner" means the Insurance Commissioner;

(2) "Department" means the Insurance Department;

(3) "Drug" means drug, as defined in section 21a-92;

(4) "Person" means person, as defined in section 38a-1;

(5) "Pharmacist services" includes (A) drug therapy and other patient care services provided by a licensed pharmacist intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, and (B) education or intervention by a licensed pharmacist intended to arrest or slow a disease process;

(6) "Pharmacist" means an individual licensed to practice pharmacy under section 20-590, 20-591, 20-592 or 20-593, and who is thereby recognized as a health care provider by the state of Connecticut;

(7) "Pharmacy" means a place of business where drugs may be sold at retail and for which a pharmacy license has been issued to an applicant pursuant to section 20-594; and

(8) "Pharmacy benefits manager" or "manager" means any person that administers the prescription drug, prescription device, pharmacist services or prescription drug and device and pharmacist services portion of a health benefit plan on behalf of plan sponsors such as self-insured employers, insurance companies, labor unions and health care centers.

Sec. 3. Section 38a-479bbb of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2013*):

(a) Except as provided in subsection (d) of this section, no person shall act as a pharmacy benefits manager in this state without first obtaining a certificate of registration from the commissioner.

(b) Any person seeking a certificate of registration shall apply to the commissioner, in writing, on a form provided by the commissioner.

The application form shall state (1) the name, address, official position and professional qualifications of each individual responsible for the conduct of the affairs of the pharmacy benefits manager, including all members of the board of directors, board of trustees, executive committee, other governing board or committee, the principal officers in the case of a corporation, the partners or members in the case of a partnership or association and any other person who exercises control or influence over the affairs of the pharmacy benefits manager, and (2) the name and address of the applicant's agent for service of process in this state.

(c) Each application for a certificate of registration shall be accompanied by (1) a nonrefundable fee of fifty dollars, and (2) evidence of a surety bond in an amount equivalent to ten per cent of one month of claims in this state over a twelve-month average, except that such bond shall not be less than twenty-five thousand dollars or more than one million dollars.

(d) Any pharmacy benefits manager operating as a line of business or affiliate of a health insurer, health care center, hospital service corporation, medical service corporation or fraternal benefit society licensed in this state or any affiliate of such health insurer, health care center, hospital service corporation, medical service corporation or fraternal benefit society shall not be required to obtain a certificate of registration. Such health insurer, health care center, hospital service corporation, medical service corporation or fraternal benefit society shall notify the commissioner annually, in writing, on a form provided by the commissioner, that it is affiliated with or operating a business as a pharmacy benefits manager.

[(e) Any person acting as a pharmacy benefits manager on January 1, 2008, and required to obtain a certificate of registration under subsection (a) of this section, shall obtain a certificate of registration from the commissioner not later than April 1, 2008, in order to continue to do business in this state.**]**

Sec. 4. Section 38a-479eee of the general statutes is repealed and the

following is substituted in lieu thereof (*Effective October 1, 2013*):

The commissioner may conduct investigations and hold hearings on any matter under the provisions of sections 38a-479aaa to 38a-479hhh, inclusive, as amended by this act, and section 1 of this act. The commissioner may issue subpoenas, administer oaths, compel testimony and order the production of books, records and documents. If any person refuses to appear, to testify or to produce any book, record, paper or document when so ordered, upon application of the commissioner, a judge of the Superior Court may make such order as may be appropriate to aid in the enforcement of this section.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2013*	New section
Sec. 2	*October 1, 2013*	38a-479aaa
Sec. 3	*October 1, 2013*	38a-479bbb
Sec. 4	*October 1, 2013*	38a-479eee

Statement of Legislative Commissioners:
Throughout section 1, "pharmacy benefit manager" was changed to "pharmacy benefits manager" for statutory consistency.

INS *Joint Favorable Subst. -LCO*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact: None

Municipal Impact: None

Explanation

This bill concerns the auditing of pharmacies. As this concerns the relations between auditing entities and private pharmacies, there is no state or municipal impact.

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State Impact: None

Municipal Impact: None

OLR Bill Analysis
sSB 955

AN ACT CONCERNING PHARMACY AUDITS.

SUMMARY:

This bill prescribes how pharmacy audits can be conducted. It specifies the duties of the entity conducting the audit and how pharmacies can validate their records. The bill requires the entity conducting the audit to provide preliminary and final reports to the pharmacy, and allows the pharmacy to appeal the final report. It limits the circumstances when a pharmacy can be subjected to a charge-back or recoupment.

Under the bill, any information collected during an audit is confidential, but the entity conducting the audit may share it with the pharmacy benefits manager (PBM) and the health insurance plan sponsor (e.g., an insurer or self-insured employer) for whom it is being conducted. The entity conducting the audit may not receive payment or other consideration based on the amount claimed or the actual amount recouped from the audited pharmacy.

The bill's provisions do not apply to audits conducted because a PBM, plan sponsor, an entity acting on a PBM or sponsor's behalf, or an employer covered under a health benefit plan reasonably suspects that that the pharmacy being audited is or has been engaged in criminal wrongdoing, willful misrepresentation, or fraud.

The bill allows the insurance commissioner to conduct investigations and hold hearings in connection with these provisions. He may issue subpoenas, administer oaths, compel testimony, and order the production of books, records, and documents. If any person refuses to appear, testify, or produce any book, record, paper or document when ordered, a Superior Court judge may make

appropriate orders upon the commissioner's application.

EFFECTIVE DATE: October 1, 2013

PHARMACY AUDITS

Under the bill, a pharmacy audit is one conducted of any pharmacy's records for prescription drugs or prescription devices it dispenses to beneficiaries of a health insurance plan. The audit can be conducted on-site or remotely by or on behalf of a PBM or health insurance plan sponsor.

Audits do not include a concurrent review or desk audit (1) that occurs within three business days of the pharmacy's transmission of a claim to a PBM or plan sponsor or (2) where the PBM or plan sponsor does not demand a charge-back or recoupment. Audits cannot cover a period of more than 24 months after the date a claim was submitted by the pharmacy to the PBM or plan sponsor unless a longer period is required by law.

The bill bars any entity other than a PBM or a plan sponsor from conducting a pharmacy audit unless the entity and manager or sponsor, as applicable, have a written agreement on how the audits will be conducted. Before conducting an audit on the manager's or sponsor's behalf, the entity must notify the pharmacy in writing that it and the manager or sponsor has executed the agreement.

DUTIES OF AUDITING ENTITY

Under the bill, any entity conducting an audit must:

1. give a pharmacy written notice at least 14 calendar days before conducting an audit;

2. not initiate or schedule an audit during the first five business days of any month, unless the pharmacy being audited expressly agrees to an audit during this time;

3. make all determinations regarding the validity of a prescription

or other record consistent with the laws governing the dispensing of prescriptions;

4. accept paper or electronic signature logs that document the delivery of prescription drug and device and pharmacist services to a health plan beneficiary or his or her agent;

5. give the pharmacist in charge a complete list of records reviewed before leaving the pharmacy at the end of an on-site portion of an audit; and

6. establish a process for a pharmacy to appeal the final audit report and disclose these procedures to the pharmacy being audited.

In addition, a licensed pharmacist must conduct or be consulted in conducting any audit that involves clinical judgment. Also, the entity conducting an audit has access only to previous pharmacy audit reports of a particular pharmacy conducted by or on behalf of the entity. The bill does not authorize access to any information that is confidential or prohibited from disclosure by law.

VALIDATING RECORDS

Under the bill, a pharmacy may use authentic and verifiable statements or records to validate the pharmacy record and delivery. These records can include, among other things, medication administration records of a nursing home, assisted living facility, hospital, or a health care provider who can write prescriptions.

A pharmacy may use any valid prescription to validate claims in connection with prescriptions, changes in prescriptions, or refills of prescription drugs. These can include, among other things, medication administration records, faxes, electronic prescriptions, electronically-

stored images of prescriptions, electronically-created annotations, or documented telephone calls from the prescribing health care provider or his or her agent. Documentation of an oral prescription order that has been verified by the prescribing health care provider can be used to validate a claim.

If an entity conducting an audit uses extrapolation (sampling records) to calculate penalties or amounts to be charged back or recouped, the pharmacy may present evidence to validate orders for prescription drugs or prescription devices that are subject to invalidation due to this method. Under the bill, "extrapolation" is the practice of inferring a frequency of dollar amount of overpayments, underpayments, nonvalid claims, or other errors on any portion of claims submitted, based on their frequency or dollar amount actually measured in a sample of claims.

REPORTS AND APPEAL

The entity conducting an audit must provide a preliminary report to the pharmacy within 60 calendar days after it concludes a pharmacy audit and before it issues a final audit report. The entity must give the pharmacy at least 30 calendar days after the pharmacy receives the preliminary report to respond to its findings, including addressing any alleged mistakes or discrepancies and producing documentation to that effect.

The entity must issue a final audit report that considers any responses the pharmacy provides within 120 calendar days after it receives any responses from the pharmacy or, if no responses are received, after the entity concludes the audit. A pharmacy may appeal a final audit report in accordance with the procedures established by the entity, which must provide at least 30 calendar days for filing the appeal.

After an appeal has been decided, the entity that issued the final audit report must provide a written determination of the appeal together with the final audit report to the pharmacy and, if applicable,

the PBM and the plan sponsor. If the pharmacy, PBM, or plan sponsor is not satisfied with the determination, it can seek relief under the terms of the contract between the pharmacy and the PBM or sponsor.

CHARGE-BACKS AND RECOUPMENT

The bill bars the entity conducting an audit or person acting on its behalf from (1) imposing a charge-back or recoupment, (2) attempting to charge-back or recoup, or (3) assessing or collecting penalties from a pharmacy until the deadline to file an appeal of a final audit report has passed or the appeals process has been exhausted, whichever is later. If an identified discrepancy in an audit exceeds $30,000, future payments to the pharmacy in excess of this amount may be withheld pending adjudication of an appeal. No interest may accrue for any party during the audit period, beginning with the notice of the audit and ending with the conclusion of the appeals process.

The bill also bars a charge-back or recoupment for a clerical or recordkeeping error in a required document or record, including a typographical, scrivener's, or computer error, unless the error actually causes financial harm to the PBM, plan sponsor, or a plan beneficiary.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable
Yea 18 Nay 0 (03/07/2013)